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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,825	03/30/2001	Fiona Duffner	10018.200-US	6134

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EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	PAPER NUMBER
1639	14

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/823,825	Applicant(s) DUFFNER ET AL.	
	Examiner Padmashri Ponnaluri	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,13,15,19-21,29,30 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,13,15,19-21,29,30 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-4, 13, 15, 19-21, 29-30 and 39; and election of species gnomic DNA and beta-lactamase, E.coli, in Paper No. 10, 2/26/03 is acknowledged.

2. Claims 40-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

3. Preliminary amendment A, cancels claims 5-12, 14, 16-18, 22-28, and 31-38.

4. Claims 1-4, 13, 15, 19-21, 29-30 and 39 are currently being examined in this application.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the complete gene of interest" in step (f). There is insufficient antecedent basis for this limitation in the claim. Further it is not clear what does applicants mean by 'complete gene of interest.' Does applicants mean complete sequence of gene of interest ? applicants are requested to clarify.

Claim 4 recites the limitation "the cDNA" . There is insufficient antecedent basis for this limitation in the claim or in claim 1.

Claim 1 is indefinite and vague by reciting 'cDNA or the cDNA Library is normalized.' It is not clear what does applicants mean by normalized'. Applicants are requested to clarify.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-4, 13, 15, 21, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO98/22491 (McCarthy et al).

The instant claims briefly recite a method for identifying and isolating a gene of interest from a gene library, wherein the gene encodes a polypeptide carrying a signal sequence for secretion, the method comprises: providing a genomic or cDNA library inserting into the library a promoter less and secretion signal less polynucleotide encoding a secretion reporter; introducing the library into a host cell; screening and selecting host cell that secretes the active secretion reporter; identifying the gene of interest into which the secretion reporter was inserted; isolating the gene of interest.

McCarthy et al disclose a method for identifying a cDNA encoding a mammalian protein having a signal sequence (refers to the gene of interest which encodes a polypeptide carrying a signal sequence for secretion of the instant claims) (i.e., see the abstract). The disclosed reference method includes the following steps: a) providing a library of mammalian cDNA (refers to step a) of the instant claims); b) ligating the library of mammalian cDNA to DNA encoding alkaline phosphotase lacking both a signal sequence and a membrane anchor sequence (refers to a DNA fragment comprising a promoter-less and secretion signal less polynucleotide encoding a secretion reporter of the instant claims) to form ligated DNA (refers to the step b of the instant claims); c) transforming bacterial cells (refers to host cells of the instant claims) ligated DNA (refers to the step c) of the instant claims); d) isolating DNA comprising mammalian cDNA ; e) transfecting DNA isolated from step d) into a mammalian cells which do not express alkaline phosphatase; g) identifying the clones in bacterial cell clone corresponding to the clone in mammalian cell clone library (refers to step d) of the instant claims); h) isolating and sequencing a portion of the mammalian cDNA present in the bacterial cell library clone identified in step g) to identify a mammalian cDNA encoding a mammalian protein having a signal sequence (refers to step f) of the instant claims) (i.e., see abstract). The reference discloses that using the method a purified DNA which includes a sequence encoding a protein (ethb0018f2). McCarthy et al disclose that the DNA sequence of ethb0018f2 revealed that the ethb0018f2 cDNA encodes a 467 amino acid reading frame (refers to the complete gene of interest and the gene encodes a protein of the instant claims) (i.e., see page 17). The reference clearly anticipates the claimed invention.

9. Claims 1-4, 19-21, 29-30 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/40146 (JACOBS et al).

Jacobs et al disclose yeast invertase gene as reporter system for isolating cytokines. The reference method for isolating cDNA encoding a novel secreted mammalian protein includes the following method steps: a) constructing a cDNA library (refers to step a) of the instant claims); b) ligating cDNA library to a DNA encoding a non-secreted yeast invertase (refers to step b) of the instant claims); c) transforming the ligated DNA into E.coli (refers to step c) of the instant claims); d) isolating plasmid DNA containing mammalian cDNA ligated to the DNA encoding non secreted yeast invertase (refers to instant claim20); e) transforming the DNA of step d) into a yeast cell which does not contain the invertease gene; f) selecting yeast cells capable of growth on sucrose or raffinose (refers to step d) of the instant claims); g0 purifying DNA; h) screening the cDNA library to detect full length cDNAs which contain novel mammalian leader sequence; I) isolating the full length cDNA (refers to step f) of the instant claims) (i.e., see summary of the invention). The reference in page 11, discloses the novel secreted and extracellular proteins of the invention encoded by the mammalian cDNA (refers to complete gene of interest of the instant claims). The reference clearly anticipates the claimed invention.

10. Claims 1-4, 15, 19, 21, 29-30 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,150,098 (ZHANG et al).

Zhang et al disclose methods for identifying novel secreted mammalian proteins in mammalian host cells. The invention provides a method for rapping signal sequence DNA from cDNA libraries and the cDNA libraries are constructed in a signal trap vector for transfection into a mammalian host cell and detecting secretion of reporter polypeptide. The signal trap

vector contains DNA encoding a reporter polyeptide which lacks a functional signal sequence. The reference method comprises the following steps: a) constructing a mammalian cDNA library (refers to step a) of the instant claims); b) inserting the cDNA library into a signal trap vector comprising DNA encoding a reporter polypeptide lacking a functional signal sequence; d) transfecting the library into a mammalian host cell lacking the functional reporter polypeptide (refers to step c) of the instant claims); e) selecting transfected mammalian cells (refers to step d) of the instant claims); f) analyzing DNA recovered from the transfected cells (refers to step e) of the instant claims); g) screening a mammalian cDNA library to identify a full-length cDNA (i.e., see summary of the invention). The reference discloses that the secretion of reporter polypeptide may be determined by growth on selective medium requiring the presence of the secreted reporter polyeptide (refers to instant claim 19) (i.e., see column 4, lines 39-42). Zhang et al disclose that a cDNA library may also be screened for genes encoding full-length secreted polypeptides by PCT using primers based upon the sequences obtained by signal trapping (refers to instant claim 30) (i.e., see column 10, lines 16-18). The reference clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-4, 13, 15, 19-21, 29-30 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over either US Patent 6,150,098 (ZHANG et al) or WO 97/40146 (JACOBS et al) or WO 98/22491 (McCarthy) and further in view of US Patent 6,468,739 (HAAS et al).

Zhang et al, Jacobs et al and McCarthy et al have been discussed supra.

The claimed invention differs from the prior art teachings by reciting the DNA fragment comprises a transposon. Zhang et al teach methods for identifying novel secreted mammalian proteins in mammalian host cells using signal trap vectors. Jacobs et al disclose yeast invertase gene as reporter system for isolating cDNA encoding a novel secreted mammalian protein. McCarthy et al disclose a method for identifying a cDNA encoding a mammalian protein having a signal sequence. Neither Zhang, Jacobs nor McCarthy teach the use of transposon in the method of identifying secretary proteins. Haas et al teach a method for identifying secretary genes from Helicobacter. The reference method steps include setting the helicobacter gene bank (refers to the genomic DNA library of the instant claims) in a plasmid vector which allows a selection for transpososn insertion on the vector DNA. The reference teaches that the transposon is coupled to a marker for secretary activity (refers to the DNA fragment of the instant claims).

Th3 preferred transposon in the reference method is TnMax9. The TnMax9 transposon carries a copy of β-lactamase gene (refers to reporter of the instant claims and instant claim 20) without promoter and signal sequence 9blaM) as a marker directly following IR (i.e., see column 5). The reference further teaches that after insertion of TnMAx9 the blaM gene fuses with target gene X. the reference teaches if gene X codes for a secretary protein, the fusion protein will be transported through the cytoplasmic membrane of E.coli into periplasm, and the fusion protein displays its β-lactamase activity. The reference identifies Helicobacter adhesin genes useful in diagnosis and prevention and treatment of helicobacter infections using the disclosed method.

A person skilled in the art would have been motivated to use the method taught by Haas et al in the method of identifying secretary proteins because Haas et al teach a method of identifying adhesin gene (secretary gene) using insertion of the genes into a transposon carrying β-lactamase as a reporter, and Zhang et al, Jacobs et al and McCarthy et al teach methods of identifying secretary genes using a promoterless and secretion signal less sequence polynucleotide encoding a secretion reporter. A person skilled in the art would have been motivated to insert the gene of interest in a transposon which is coupled to a marker, such that a larger fragment of DNA can be inserted and also the identified gene would be analyzed efficiently using Haas et al method.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884. The examiner is on Flex Schedule and can normally be reached from Monday through Friday between 7AM and 3.030 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

pp
18 September 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER